Attachment F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

N-141327-A-0000-OT

Merial Limited
Attention: Katherine Allran
Technical Director, Regulatory Affairs US
3239 Satellite Blvd.
Duluth, GA 30096

Re: Request for original approval of LONGRANGE Extended-Release Injectable Parasiticide

Dear Dr. Allran:

We approve your original new animal drug application (NADA) for LONGRANGE Extended-Release Injectable Parasiticide for Cattle dated March 30, 2011, under section 512(c)(1) of the Federal Food, Drug, and Cosmetic Act (the act). LONGRANGE (eprinomectin) Extended-Release Injectable Parasiticide is approved in cattle on pasture for the treatment and control of the following parasites:

Gastrointestinal Roundworms
Cooperia oncophora - Adults and L_4
Cooperia punctata - Adults and L_4
Cooperia surnabada - Adults and L_4
Haemonchus placei - Adults
Oesophagostomum radiatum - Adults
Ostertagia lyrata - Adults
Ostertagia ostertagi - Adults, L_4, and inhibited L_4
Trichostrongylus axei - Adults and L_4
Trichostrongylus colubriformis - Adults

Lungworms
Dictyocaulus viviparus - Adults

Grubs
Hypoderma bovis

Mites
Sarcoptes scabiei var. *bovis*

Persistent Activity

LONGRANGE (eprinomectin) has been proven to effectively protect cattle from reinfection with the following parasites for the indicated amounts of time following treatment:

Parasites	Durations of Persistent Effectiveness
Gastrointestinal Roundworms	
Cooperia oncophora	100 days
Cooperia punctata	100 days
Haemonchus placei	120 days
Oesophagostomum radiatum	120 days
Ostertagia lyrata	120 days
Ostertagia ostertagi	120 days
Trichostrongylus axei	100 days
Lungworms	
Dictyocaulus viviparus	150 days

The expiration dating for this new animal drug is 18 months. We forwarded a notice of this approval for publication in the FEDERAL REGISTER. You must notify us of any change to the conditions established in this approval according to 21 CFR 514.8. Any change to the conditions of the approval may require the submission of a supplemental application.

As of the date of this letter, LONGRANGE Extended-Release Injectable Parasiticide qualifies for THREE years of marketing exclusivity under section 512(c)(2)(F)(ii) of the act.

Your final printed labeling must be identical to the approved labeling submitted March 30, 2011 (N-141327-A-0000-OT, package insert, 50 mL bottle, 50 mL carton, 12 X 50 mL display carton, and the 12 X 50 mL shipper carton and labeling). Please submit a single copy of each component of the final printed labeling before distributing and marketing your new animal drug. If labeling is submitted via eSubmitter, the labeling should be provided in Portable Document Format (.pdf) files, which are an exact electronic representation of the final labeling. Any changes to this approved labeling will require a supplemental application (see 21 CFR 514.8(c)).

Under current good manufacturing practice (cGMP) regulations (21 CFR parts 211 and 226), you are required to validate your manufacturing processes. This validation provides assurance that the manufacturing processes will reliably meet predetermined specifications. This validation is demonstrated by documenting that the manufacturing processes are adequate to preserve the identity, strength, quality, and purity of the new animal drug. If your validation information was not available or was found deficient at the time of the pre-approval inspection, you should contact FDA after you complete manufacturing validation and before you ship the product. A product that does not conform to cGMP is adulterated under section 501(a) of the act.

If you submit correspondence relating to this approval, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Cindy L. Burnsteel, DVM, Director, Division of Therapeutic Drugs for Food Animals at 240-276-8341. You may also contact

Janis R. Messenheimer, DVM, Leader, Antiparasitic and Physiologic Drugs Team at 240-276-8348.

Sincerely,

{see appended electronic signature page}
Bernadette M. Dunham, D.V.M., Ph.D.
Director
Center for Veterinary Medicine

Enclosure:
Freedom of Information Summary

Electronic Signature Addendum for Submission ID

N-141327-A-0000-OT

Signing Authority (Role)	Letter Date
Bernadette Dunham (Center Director)	9/26/2011

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.